The introduction of new interventional procedures in the British National Health Service – a qualitative study

INTRODUCTION

Interventional procedures (IPs) are health technologies used for diagnosis or treatment involving an incision, puncture, entry into the body cavity or the use of electromagnetic radiation.[1] They are the least regulated type of health technologies. Decisions regarding their introduction into the National Health Services (NHS) lie within the individual Trusts (England and Wales) or Boards (Scotland). Currently, there is no prescribed way to do this.

We therefore undertook an exploratory qualitative study to describe and understand the current processes of introduction of IPs into clinical practice. This study was designed to explore experiences and perceptions of NHS decision-makers regarding how they handle new IPs and to identify problems areas for improvement. How NHS decision-makers respond to IPs with NICE IP guidance has been reported elsewhere.[2]

METHODS

Participants and setting

As healthcare delivery is organised differently across the UK, a purposive sampling strategy was adopted to select NHS employees in England, Wales and Scotland representing different roles, types and sizes of practices (Table 1). Sampling in qualitative research is normally non-random as the aim is not to obtain an 'on average' view of a wider population, but instead, to gain an in depth understanding of the experience of particular individuals,[3] and to reflect the diversity within a given population[4] (we were particularly interested in variation in approaches and perceptions). We chose decision-makers who were involved in one or more of the following activities, as people with these roles are likely to be those who influence the uptake of new interventional procedures:

- Decision-making about how resources should be used in the NHS;

- Prioritisation of new interventional procedures in the NHS, and
- Delivery of interventional treatment to patients in the NHS.

The professional roles of decision-makers who were invited to participate included chief executives of Trusts or Health Boards, medical directors, clinical directors, consultant surgeons, public health consultants.

The sample consisted of 18 decision-makers who were identified in three ways: from a list of known committee members of the IPP[†]; an NHS network group with an interest in public health; and subsequent snowball and convenience sampling. Committee members of the IPP were targeted because their professional roles indicated that they were active locally in decision-making about interventional procedures. Moreover, being part of the Programme meant that they would be familiar with the topic under investigation. Participants were also drawn from the NHS network group because it was mainly represented by public health consultants who predominantly work at the commissioner side of the NHS and hence are likely to play an important role in regulating what is offered to patients. This sample was chosen to describe a range of knowledge interpretation and general awareness. A recruitment letter with details about the study was e-mailed to every person contacted.

Data collection

Data was generated from NHS decision-makers using one to one, face to face semi-structured interviews, at a time and venue convenient for the participant. Prior to the interview, participants received a 'participant information leaflet' explaining study's objectives and purpose of the interview. All participants signed a consent form at the beginning of the interview. Using an interview topic guide, participants were asked open-

[†] The Interventional Procedures Advisory Committee members include the following job titles: chief executives, medical directors, clinical directors; academic researchers; patient representatives.

ended questions exploring (1) the current process of introduction of new IPs at the participant's place of work, (2) any problems with and potential improvements to the current process. Data were digitally recorded and transcribed verbatim.

Data analysis

Data was entered into NVivo (v.7 computer software, QSR International, Melbourne, Australia) for coding and analysis using techniques drawn from the framework approach.[4,5] A coding frame was developed based on our initial research questions and emerging themes from the transcripts. Two researchers systematically coded the transcripts. Thematic categories were developed by further refining the initial coding frame and thematic charts were checked by at least one other researcher within the team.

Models characterising the current process of introduction of new IPs in the NHS were developed through a systematic synthesis of the framework charts whereby similarities and differences were identified and compared across respondents.

Different organisational arrangements of the NHS are in place in England, Scotland and Wales, however, regardless of country, NHS organisations can be broadly divided into commissioner and provider of services. Decision-makers' views for both types of organisational arrangements were explored, and a stratified data-analysis was conducted in order to identify potential subgroup differences in how new IPs are handled and perceived by commissioners and providers.

RESULTS

Out of the 18 decision-makers contacted, 15 replied and agreed to be interviewed, although an interview time could not be set for one. Fourteen interviews were conducted by one researcher over a period of four months in 2008. The sample varied in relation to setting, type of organisational structure (commissioner or provider) and role in the

decision-making process (Table 1). Respondents were widely dispersed: nine from England (six of ten Strategic Health Authorities), four from Scotland and one from Wales.

Management strategies of new interventional procedures

Provider organisations

The procedure for deciding whether and in what way to introduce new IPs in local clinical practice varied across settings, between clinical directorates, and within provider organisations. It was found that some centres had more structured processes than others:

K120: "I don't think there is a formal process. For a lot of new procedures, they are introduced ad hoc by individuals who are interested in doing something different."

N123: "…if a surgeon wants to introduce an IP they have to apply through the different channels and actually have to put forward a business case to use that intervention even though it might be seen in other areas as a recognised acceptable treatment."

However, patterns were identified enabling the development of broad conceptual models (Figure 1). The process ubiquitously starts with a clinician wanting to deliver a new IP. Some respondents described how this was initially followed by informal discussions with peers and the clinical director responsible for the service:

D114: "…all new procedures or variations in procedures should be discussed with colleagues prior to undertaking them, except in an emergency."

E115: "… the clinician would, firstly, discuss with his own colleagues within the directorate about the appropriateness of how a new procedure might fit with the clinical service…."

One respondent described how the clinical director had the responsibility for deciding whether the IP should be notified to a special group or committee for further evaluation whereas in other centres, the clinician wanting to introduce the IP directly notified the group/committee. Such groups/committees generally had an executive role, although in

one centre the group/committee had an advisory role only and the clinical director had full autonomy as to whether to implement the advice in order to avoid conflicts with the clinical director's role:

D114: "…if we say [the group] has got the power to say yes or no, and the poor clinical director is the one who has to fund it, then what you can get is consultants going off… 'I want to do this. I've got permission from [the group]… And the poor clinical director with financial control says, 'ahhhh, I've lost my responsibility because it has been taken by somebody else!' Which is why [the group] was specifically set up so that it couldn't undermine the clinical director's role."

In general, membership of these groups/committees included not only clinical representatives, but also managers, and ethics and patient representatives. Following agreement to 'credential' the clinician to carry out the procedure, most respondents described the necessary preparation of a business case for new IPs that had cost-consequences while appearing to provide additional benefits to patients or had the potential to improve survival. Business cases were generally prepared by the clinician making the request. In one centre, commercial sponsors often offered to prepare business cases for clinicians:

N123: "The onus is definitely on the clinician, we [clinicians] may not have... any financial acumen in how you present the business case… and they [clinicians] might not have time to actually prepare that business case. What some reps do is that they will prepare a business case for you…"

The content of business cases was similar across centres with minor variations (Box 1). Although presentation of a business case to the decision-maker holding the budget is part of the formal process, resources are often secured from sources external to the NHS. In those centres where a committee/group is in place to address these issues, who makes the decision following the business case would be the committee/group. In the centre in

which the committee is only advisory, the individual holding the budget would be the ultimate decision-maker. In the other two centres, this was unclear.

Despite a process being in place for the introduction of procedures, a perception was expressed that clinicians often do not adhere to it:

B112: "some people won't necessarily know that they're supposed to do that [formal process], I'm not sure how anyone in the trust knows that that's happened [procedures], to be absolutely honest."

A111: "…the clinicians, if they choose not to tell you about it and they can find somebody to give them the kit, they just get on and do it."

Two respondents (E115, K120) described how the sole decision-makers for the introduction of a new IP can be the clinicians themselves, with no clear regulatory body within the hospital enforcing the safe and appropriate introduction of new IPs.

Commissioner organisations

Minor variations were observed in the role of commissioner organisations in the introduction of new IPs (Figure 2). All respondents described how their centres had a reactive process with the majority being started by clinicians and/or patients proposing procedures to a group/committee. In one centre there was the expectation for provider organisations to inform commissioners about IPs that have immediate cost-consequences prior to introduction:

G117: "... if it's an increased cost or if it's a change in service, we would expect them [providers] to come back and discuss that with our Commissioning Department Directorate."

One respondent described a less structured procedure than the rest:

J119: “Drugs have a very structured process, but I would say there’s not a parallel structured process for other interventions.”

In contrast, the expectation, as described in another centre, was that provider organisations should always ask the commissioners whether they can introduce a new service; and another respondent believed that requests for IPs would always go to the commissioner, due to the tight financial state of provider organisations.

The development of a business case was a compulsory stage in the process for all commissioning centres studied regarding IPs considered as potentially being an improvement of services but having immediate cost-consequences. Business cases were generally prepared by individuals tasked to do this within the organisation although one respondent indicated that the clinician making the request was expected to produce the business case with help from a person tasked at management level. The content of business cases was similar to that produced in provider organisations (Box 1). However, in one centre, the commissioners also sought an opinion from the clinician requesting the service and from the hospital.

One respondent described the process as ‘messy’ (C113) and another as ‘complicated’ and ‘tortuous’, but the complexity was not seen by the decision-maker as such a hindrance that the process did not work (H118).

Factors affecting the decision to introduce interventional procedures

Table 2 summarises factors that were identified during the interviews, which can potentially affect decision-making about the introduction of IPs and their effect on adoption as perceived by the decision-makers.

Provider organisations

A common factor was cost. It was perceived by all that extra costs of a new IP (such as a new device, disposable kit, or if it is a totally new technique requiring a new programme of care) is the main obstacle to its introduction in the context of a constrained funding environment. Such resource implications have to be considered against the likelihood of higher patient benefits:

B112: "…I think as a committee in the trust we would not exclude something because it's a more expensive treatment option…"

Other factors influencing the introduction of IPs were manufacturer/company incentives, the attitude towards the IP and support of colleagues:

D114: "…the important thing is that there is a sufficient body of support from the professionals to be able to accept that this is a reasonable thing to undertake…"

Some argued that sometimes it is difficult to fulfil the specifications set by the decision-maker and that some procedures are judged as being too innovative hence lacking in evidence. It was perceived by one respondent that it may be hard getting new treatments introduced if the IP is carried out only in one or two other countries:

F116: "…if the Norwegians and the Swedes are doing it, they are generally not known to be desperately adventurous in what they're doing. If they got research evidence that supports it then what's the problem?"

One issue raised was potential conflicts of interest in members of the decision-making committee:

N123: "... one of the people that was sitting on the panel, his wife required the procedure and I had been asking for this to be introduced quite a lot, but I think there was a personal interest, so we were allowed to do it, but only on a patient named basis… It helped other patients… but we haven't introduced the kit commonly…"

Motivators for decisions to introduce a new procedure that were mentioned by respondents included: numbers affected (depending on the cost of the technology, this could be a motivator or not), minor variations in practice, reduced cost, trained and competent operators, evidence of benefits, and 'positive' NICE guidance.

Commissioner organisations

As with provider organisations, issues related to increased cost (i.e. affordability, financial state of the organisation, training requirements) were viewed by all commissioners as significant barriers. Other factors mentioned were: pressure from the public and policy-making organisations, what other organisations are offering, and whether the new procedure supports the overall aims and priorities set by the organisation's board:

G117: "When something costs peanuts… then the decision is much more likely to be favourable, than when something costs hundreds of thousands."

M122: "If a procedure becomes very well known, then sometimes we get additional pressure [from the public]."

Perceived potential barriers to an effective response to new interventional procedures

Provider organisations

Although respondents were clear about the type of information needed for decision-making, it was recognised that the assessments carried out by the groups/committees are not always clear and transparent:

F116: "…I'm not sure how scientific we are in the valuation [of procedures]. It's probably an emotional feel; this is just a better service than something… this has the ability to be better than something else."

It was noted that it is difficult to monitor what goes on in the provider organisations. This is mainly due to the lack of coding (and registers) of new IPs and as a consequence they depend on nursing staff and on reviews of case notes to identify IPs that are not standard practice:

A111:" The biggest problem with all of them is that not a single one of them… comes with an OPCS [Office of Population Censuses and Surveys] code, which means that when the coders come to do them, they call them something else."

The role of commissioner organisations in the introduction of IPs was considered 'obstructive' by some respondents with a perception that they only fund procedures if they have been required to do so. It was also noted that it can take a long time for clinicians to produce business cases because firstly, data on prevalence and incidence are very difficult to come by, and secondly, clinicians lack information on how much it costs the NHS per day for treating a particular type of patient.

Commissioner organisation

The main problem perceived by some commissioner organisations was that it is difficult to know what provider organisations are actually doing, and therefore difficult to stop procedures with safety concerns:

G117: “the difficulty is that actually we don’t necessarily know what the trusts are doing…In fact, it’s unlikely that the trusts themselves will necessarily know the details of exactly what every single practitioner within that trust is doing… in theory we would be able to stop something that we thought was unsafe or that we did not any longer want to pay for. In practice, I’m not sure how often that happens.”

Q125: “… I’ve discovered recently that we’re using it [a procedure] … nobody told us, as it has been used as part of the wound healing process by our district nurses… I can see where things can be going on without people knowing, and they obviously decided to introduce it without going through the committees.”

Suggestions for improvements of the current process of introduction of interventional procedures

Provider organisations

Three respondents felt that the system used to introduce IPs is satisfactory, but they acknowledged that there is some room for improvement in their own organisations, particularly in relation to the workforce available, and making the process smoother:

D114: “I think we handle it as good as possible… if one was more meticulous and had a bigger number of people to help in clinical governance, I think we would like to complete the loop better...”

A111: “I’m happy with what we’ve got, but I’m conscious that is not how it is done around the country and we’re still learning as we go along. Even seven years in now, we’re still developing the process and making it smoother and it’s gradually changing with time, but all of the fundamentals are in place and it all works very well.”

A couple of respondents highlighted the need to see a more formal process of introduction of procedures in their organisation:

E115: “I think that’s [the process] probably something that could be improved or if it exists it should be better advertised… The process probably needs to be more formalised and I think that the clinicians need to be familiarised and engaged in the process of generating those protocols and also know how to refer to them.”

K120: “I’d like to see a proper mechanism so that if anybody wants to introduce anything that’s new… that would have to go through a formal process. And that formal process would allow checks to be made as to what NICE was saying, what national associations were saying and anybody else who’d form an opinion about these things, so that you could get a robust mechanism for checking that opinion across the spectrum of whether it is a good thing that is trying to be introduced.”

A need for more robust mechanisms for monitoring was a common concern amongst respondents. Some participants, therefore, wanted to see better systems and thought that having a register to help monitoring procedures would be a helpful start:

D114: “We need to have registers of new procedures and old procedures, for that matter the ones that are doubts about their efficacy or safety, we should have many more better methods of collecting the data than we have at the moment.”

In terms of information required for decision-making, one participant suggests that health authorities should have information available so that clinicians could access it in order to inform business cases.

Commissioner organisations

Two respondents acknowledged that the process could be improved, but found it difficult to identify what in particular could be improved. One respondent felt that the process should

be faster so that they could get quicker responses and greater influence in changing services.

H118: "…we should speed it up so we get quicker responses around what people are planning to do. Particularly if it's going to cost money, and they want to do it. Because the quicker we know about it, the greater influence we've got on the commissioners to actually do things in a different way."

Another felt that the commissioner organisations need to acknowledge that the process is going to be driven from the bottom up i.e. by clinicians. Better funding arrangements for a new IP were also cited as an area that needs to be improved:

Q125: "…we're struggling to identify sufficient resources for routine practice … it's difficult to see a situation where we'd have sufficient resources to begin to introduce new technologies."

DISCUSSION

To our knowledge, this is the first study to describe how new IPs are introduced into clinical practice in the British NHS. We interviewed 14 NHS decision-makers which provided a range of views and experiences.

This exploratory study showed significant variation in how new IPs are introduced into clinical practice across the different provider centres. Some have a very structured and transparent process, including committees or groups and the development of business cases. Others use a much less structured approach in which the clinician wanting to introduce the procedure is the sole decision-maker, and business cases are prepared only if funds are required to continue to provide the treatment. At commissioner organisations the variation identified across centres was less. Although most had a process, it was evident that new IPs were not considered a priority.

The lack of a standard approach is not unique to the UK, but rather a worldwide concern. Sharma and colleagues[6] demonstrated that there was no structured, explicit process for making decisions about introducing new surgical technologies in Canada. Such lack of a decision-making process can be a barrier to the safe and efficient uptake of new health technologies.

Our study found that immediate cost and resource use were key factors in determining whether or not a new procedure is adopted. Nevertheless, the overriding determinant was the balance between costs and benefits. This study also identified several other factors that play an important role in decision-making. One is the availability of different types of evidence; another is the extent of current use of the technology in other centres.

The monitoring of the use of procedures was perceived by participants as an area that needs to be improved. A number of interviewees argued that better methods of collecting data on outcomes for each new procedure should be implemented. The lack of unique coding and registries was seen to hinder the successful monitoring of procedures after their introduction.

This study also suggests that the role of providers and commissioners in the decision-making process of introduction of new procedures is not clearly delineated. It appears that the process at commissioner organisations often starts when funds are required to continue providing it. Moreover, it was reported that it is difficult for commissioners to know what is happening at the provider side. Provider organisations on the other hand, felt that the role of commissioners could be obstructive. On this basis, it seems that better communication between organisations would likely improve the introduction of new procedures within the overall scheme of the NHS. Perhaps both types of organisations should recognise that new procedures will be handled differently, accept independent process, and identify overlaps in their management structure.

Although an attempt was made to develop decision-making models reflecting the process of introduction of new IPs in the NHS, it should be noted that the process was not always clear. This may be because it is not as transparent as it should be, or that the centre does not often deal with new IPs.

Strengths and weaknesses of the study

The use of a qualitative approach was an appropriate method to explore variation in how new IPs enter routine clinical practice. It allowed a detailed exploration of a complex area, making feasible the identification of factors, key problems and potential improvements in the processes for introducing new procedures. Although this is an exploratory study, it did successfully highlight the variation in the process of introduction of new IPs across and within NHS organisations. Moreover, participants purposefully came from a diverse background reflecting different organisational structures within the NHS, aiming to identify variation in the wider UK context.

Our study has some limitations. It relied on the reported perceptions and experiences of decision-makers, and then may not fully represent actual local practice. It is possible that participant's exposure to decision-making in relation to IPs may have been atypical and therefore their views might not be representative of the NHS as a whole. Moreover, it is important to emphasise that this study does not describe how frequently the various approaches are actually used in the NHS, but it does indicate variability in the processes, which was our purpose.

Furthermore, although the sample was purposively identified, it is possible that further variation in approaches might have been identified had more people been interviewed. As described in the results, there was consistency across interviewees, suggestive of saturation. The sample size of 14 represented a balance between reliable identification of significant variation, and logistical and practical constraints within a broader programme of

work. However, the 14 participants interviewed came from a total of 12 different NHS administrative regions in the UK, which enabled the identification of a range of knowledge, interpretations, and general awareness towards the regulation of IPs making the findings relevant to other centres in the wider UK context.

Conclusion

The objective of this paper was not to judge the quality of care of patients in the British NHS, but to highlight areas that could be improved. Although faced with the challenges posed by the rapid technological advancement, undoubtedly clinicians' primary interest is to deliver the best possible level of care to their patients. The introduction of new IPs is an area of high complexity and paramount uncertainty and a 'perfect' process is yet to be developed. This study showed that the process of introduction of new IPs in the NHS can be improved. The results of our study can be used to inform and help shape future processes of managing and introducing new procedures into the NHS.

Competing interests

None.

Ethical approval

Not required.

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Box 1 Types of information considered for the development of business cases in the NHS

Efficacy	Safety
Alternative treatments	Benefits
Training	Numbers affected
Cost	Length of stay
Potential savings	Preoperative assessment
Duration of procedure	Cost-effectiveness

Figure 1 Models of introduction of new interventional procedures in the NHS – provider

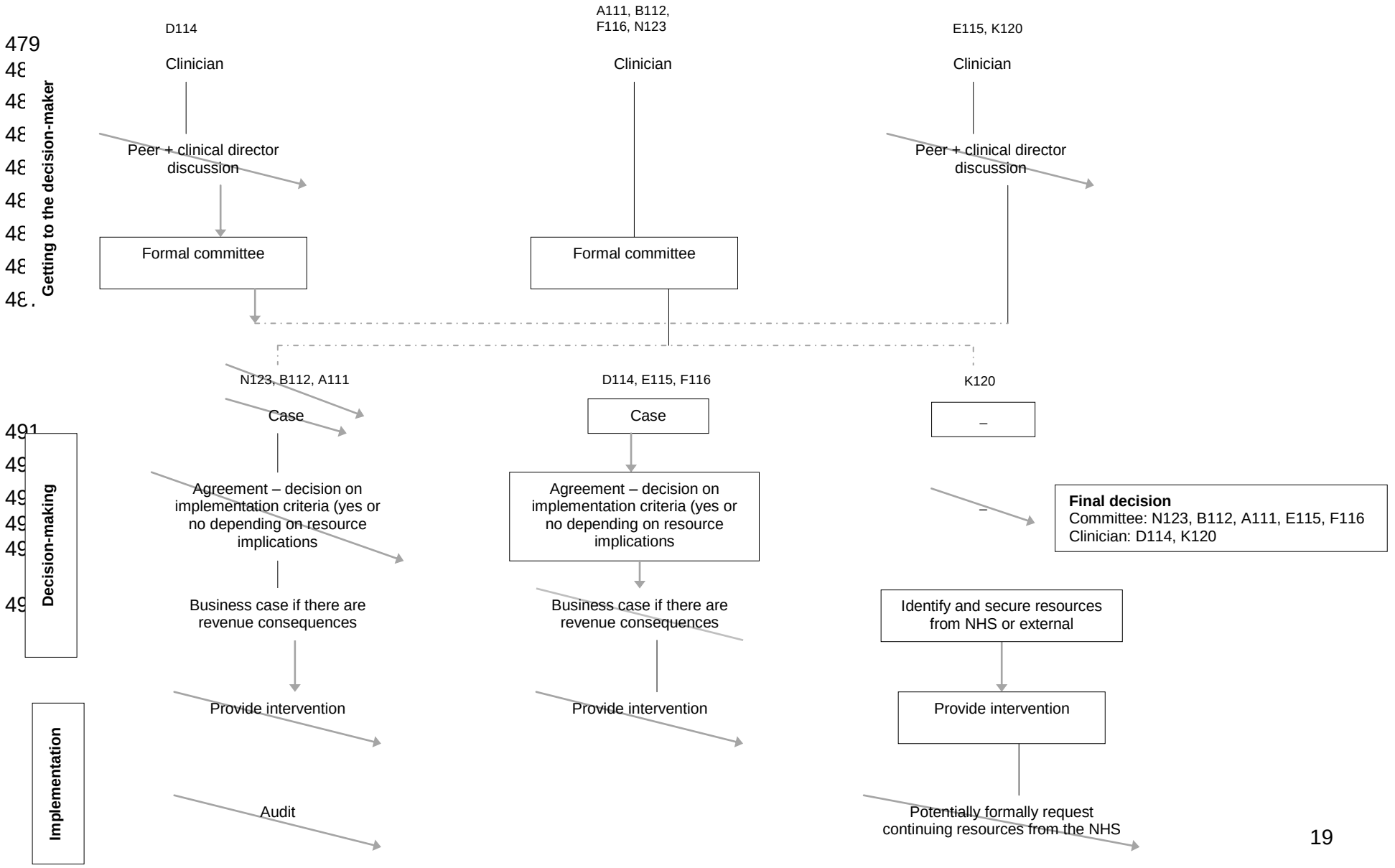

Figure 2 Models of introduction of new interventional procedures in the NHS – commissioner

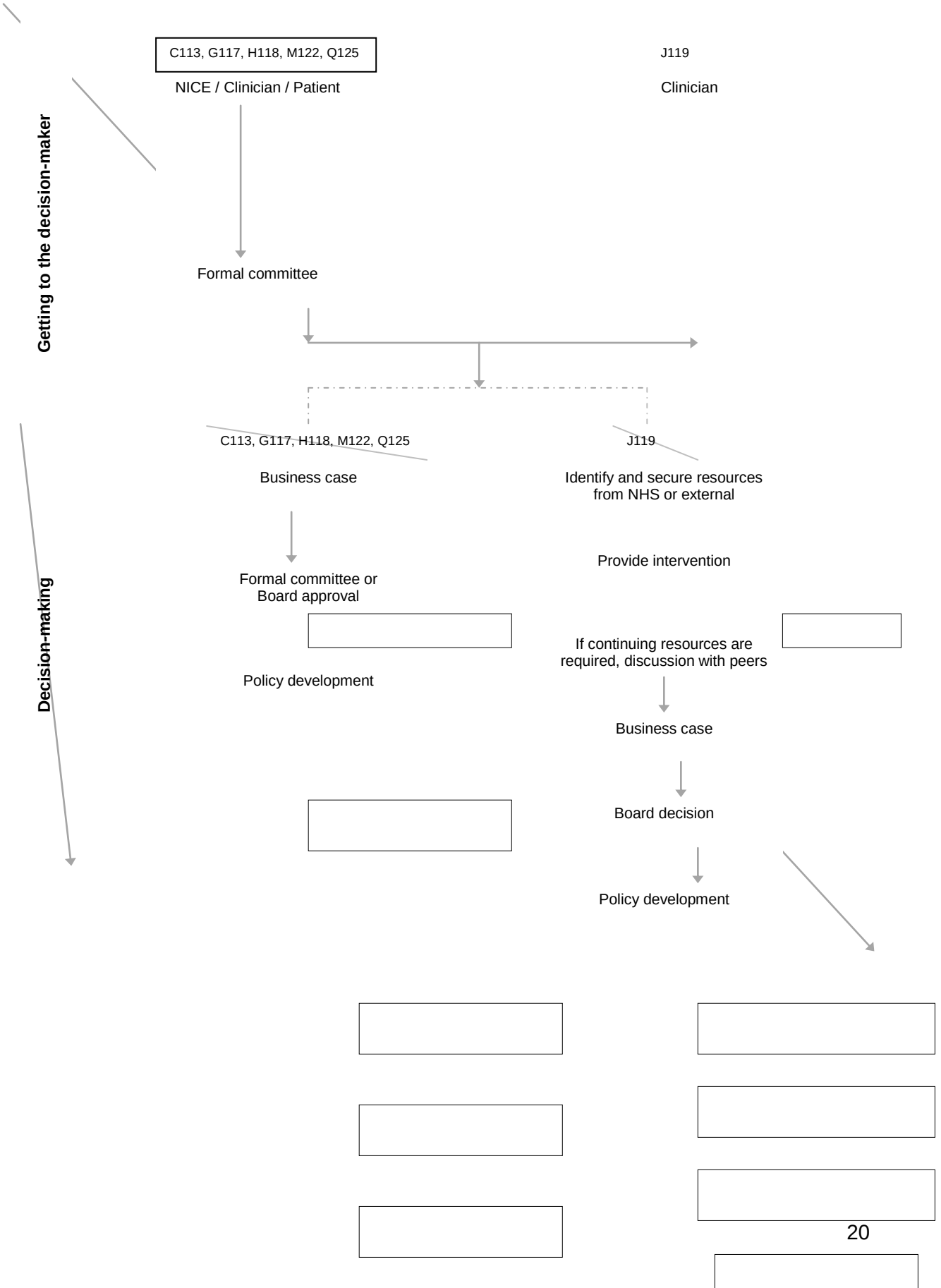

Table 1 Characteristics of the sample interviewed

Code	Title	Type of institution	Population served[†]
A111	Clinical consultant	Provider	290,000
B112	Clinical consultant	Provider	280,000
C113	Public health consultant	Commissioner	90,000
D114	Medical director	Provider	290,000
E115	Clinical director	Provider	320,000
F116	Chief executive	Provider	>800,000
G117	Public health consultant	Commissioner	150,000
H118	Director of commissioning	Commissioner	220,000
J120	Public health consultant	Commissioner	540,000
K120	Clinical consultant	Provider	540,000
M121	Public health consultant	Commissioner	2,560,300
N123	Clinical director	Provider	540,000
P123	Policy-maker	Policy-making	5,140,000
Q124	Public health consultant	Commissioner	250,000

[†]Rounded to the nearest 10,000. Source: Population Estimates Unit, Office for National Statistics – Mid 2007 population estimates.http://www.statistics.gov.uk/statbase/Product.asp?vlnk=15106

Table 2 Factors affecting the decision to introduce interventional procedures

Provider		Commissioner	
	Effect on adoption		**Effect on adoption**
- Higher cost	-	- Higher cost	-
- New kit	-	- Public / Policy-maker pressure	+
- Minor variations of practice	+	- Horizon scanning	+
- Manufacturer / Company incentives	+	- Other commissioners not offering similar treatments	-
- Support from colleagues	+	- Meets aims and priorities set by the management board	+
- Overly innovative	-	- Benefits	+/-
- Nature of people sitting in committee (conflicts of interest)	+/-	- NICE guidance	+/-
- Types of evidence i.e. prevalence, incidence, safety, efficacy, effectiveness, cost-effectiveness, training needs.	+/-		

(+): positive effect on adoption; (-): negative effect on adoption